Press Release

Abivax Receives First Phase 2b Ulcerative Colitis Clinical Trial Authorization, Provides Update on Progress of ABX464 Clinical Development Plan in Inflammatory Diseases

ABX464 advancing into Phase 2b dose-finding trial in ulcerative colitis, to be conducted in 232 patients with moderate to severe disease in up to 150 study sites in >15 countries

Study recently fully authorized in Canada as first country, with First Patient in (FPI) scheduled during Q2 2019

Phase 2a trials for rheumatoid arthritis and Crohn's disease scheduled for FPI in Q2 2019 and Q3 2019, respectively

Ulcerative colitis Phase 2a induction and 9-months maintenance data selected for oral presentation at Digestive Disease Week on May 21, 2019 in San Diego, California

PARIS, April 30, 2019, 8:00 a.m. (CEST) – Abivax (Euronext Paris: FR0012333284 – ABVX), a clinical-stage biotechnology company harnessing the immune system to develop treatments for inflammatory and viral diseases as well as cancer, announced today that Canada is the first country to have fully authorized its phase 2b clinical trial design for ABX464 to treat ulcerative colitis (UC). The first patient is expected to be enrolled in the study in Q2 2019. In addition to Canada, the clinical trial will largely be conducted in Europe.

"The January 2019 publication of ABX464's novel mechanism of action in Nature Scientific Reports and the excellent results from our Phase 2a induction and ongoing maintenance study in UC patients has further validated our decision to accelerate the development of this highly differentiated, oral, first-in-class therapeutic candidate," said **Professor Hartmut J. Ehrlich, MD, Chief Executive Officer of Abivax**. "*We have received full clearance for the Phase 2b study in ulcerative colitis by the regulatory authorities and ethics committee in Canada, the first country to approve of those to which applications were submitted, and we expect the first patient to be enrolled during the second quarter of 2019."*

Professor Ehrlich continued, *"In addition to the observed effects of ABX464's unique mechanism of action, preclinical and clinical data also suggest a broadly applicable anti-inflammatory effect, which has prompted the preparation of phase 2a clinical trials of ABX464 in Crohn's disease and rheumatoid arthritis. The phase 2a clinical trial in rheumatoid arthritis has already been submitted to regulatory authorities in several countries for approval, and clinical trial applications for a phase 2a study in Crohn's disease will be submitted in the coming weeks. Based on the data we have in hand, we are confident we can build strong shareholder value with these new studies."*

Prof. Séverine Vermeire, M.D., Ph.D., Department of Gastroenterology - University Hospitals Leuven, Belgium, past President of ECCO and Principal Investigator of the study commented: "*We look forward to initiation of this Phase 2b trial in which we hope to confirm the exciting findings from the Phase 2a trial, which will be reported at DDW, as well as determine the optimal dose for Phase 3 pivotal studies."*

ABX464 in Ulcerative Colitis

The new Phase 2b trial (link to ClinicalTrials.gov) is a randomized, double-blind, placebo-controlled, dose-ranging study in 232 UC patients that will have four arms: three escalating doses of once-daily oral ABX464 (25 mg/day, 50 mg/day and 100 mg/day) and placebo. The study, which is to be conducted in up to 150 sites in more than 15 countries, will be run under the leadership of its steering committee (Prof. Severine Vermeire, M.D., Ph.D., Prof. Herbert Tilg, M.D. Ph.D., Prof. Xavier Hebuterne, M.D., Ph.D., and Prof. William Sandborn, M.D.) and includes a sixteen week induction phase followed by an open-label maintenance study. The primary endpoint is reduction in modified Mayo Score at 8 weeks, and secondary endpoints will include clinical remission, endoscopic improvement and biomarker fecal calprotectin. Full regulatory and ethics approvals have already been granted in Canada, with first patient enrollment expected in Q2 of this year and top-level results from the study expected around the end of 2020.

In September 2018, Abivax reported impressive top-line safety and efficacy data from its phase 2a induction clinical trial ABX464-101 in patients with moderate to severe UC. The final data from this 2-month double-blind, placebo-controlled clinical study in 32 patients indicated that oral, once-daily 50mg ABX464 was safe, well-tolerated, and demonstrated statistically significant efficacy based on both clinical and endoscopic endpoints in this study. Details on the induction study results can be found in Abivax's September 04, 2018 press release.

At the end of the completed 2-month induction study, 22 of the 32 enrolled patients, (15 previously treated with ABX464 and 7 who had received placebo) opted to enroll in a 12-month open-label maintenance study, ABX464-102, which has since been increased to 24-months duration. At month six, 19 of the 22 patients were still in the study receiving a once-daily, oral capsule of 50mg ABX464. The 6-month interim analysis showed that ABX464 continued to have a good safety profile when administered chronically, and that patients continued to improve their clinical condition during this maintenance treatment (refer to ECCO release here). Currently, all 19 patients have remained in the trial to this point and have continued dosing with ABX464, with a mean and median treatment duration of greater than 12 months for the cohort, with the longest patient having been treated daily for over 17 months. The 9-months interim results of this ongoing study, which includes data from several patients already in the second year of maintenance treatment, will be announced during an oral presentation at Digestive Disease Week (DDW) on May 21, 2019 in San Diego.

ABX464 in other Inflammatory Diseases

Based on mechanistic and clinical data from studies of ABX464 validating its broad therapeutic applicability in inflammatory indications, Abivax is also preparing two additional international phase 2a clinical studies of ABX464 in rheumatoid arthritis and Crohn's disease, in 60 and 30 patients respectively. Study planning is well advanced, with first patient enrollment scheduled in Q2 for the rheumatoid arthritis study (link to ClinicalTrials.gov) and Q3 for the Crohn's disease study (link to ClinicalTrials.gov).

The inflammatory disease space represents an area of high unmet medical need, and a corresponding substantial market opportunity. It is estimated that nearly 1 million patients with ulcerative colitis live in the US, 650,000 in Europe, and over 2.7 million globally, representing a potential market opportunity of up to $5.5 billion annually, based on 2017 pharmaceutical sales in this sector. For IBD (UC and Crohn's disease), pharmaceutical sales during this same period are estimated to have reached $15 billion. The market potential for the full range of inflammatory conditions (including neuro-inflammatory diseases) is currently estimated to be in excess of $70 billion, a market and patient population that the Company believes could benefit from ABX464.

CALENDAR OF UPCOMING EVENTS:

- May 21, 2019: Oral presentation of induction and 9-months maintenance data from ABX464 phase 2a clinical trial during DDW in San Diego, CA
- October 19-23, 2019: Planned presentation of 12-months maintenance data with ABX464 in UC (including endoscopy) at annual United European Gastroenterology (UEG) week in Barcelona, Spain

About ABIVAX (www.abivax.com)

ABIVAX is mobilizing the body's natural immune machinery to treat patients with viral infections, autoimmune diseases and cancer. A clinical-stage company, ABIVAX leverages its antiviral and immune enhancing platforms to optimize candidates to treat ulcerative colitis and other inflammatory diseases, viral diseases and liver cancer. ABIVAX is listed on Euronext compartment B (ISIN: FR0012333284 – Mnémo: ABVX). More information on the company is available at www.abivax.com/en. Follow us on LinkedIn and Twitter @ABIVAX_

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